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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/025,690	02/18/98	HAUL N	5/1213

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EXAMINER	
ROTMAN, A	
ART UNIT	**PAPER NUMBER**
1612	8

DATE MAILED: 07/14/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/025,690	Applicant(s) Norbert Hauel et al.
	Examiner Alan L.Rotman	Group Art Unit 1612

☒ Responsive to communication(s) filed on *May 6, 1999* .

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *18-33* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *18-33* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

In response to the Official Office Action mailed January 22,1999, (Paper No.5) applicants attorney has canceled the original set of claims and presented a new set of claims in the Amendment filed May 6,1999 (Paper No.7) commensurate with the elected invention Group 11 respectively.Accordingly, claims 18-33 are before the undersigned Examiner for a second complete examination on the merits.

Claims 18-22 are rejected under 35 U.S.C.§101 and §112(first par.) on the grounds of an insufficient disclosure of utility.Specifically, the terms "and salts thereof" at the end of the involved claims includes toxic salts such as **"arsenites,arsenates,hydrocyanates" and the like which would render the claimed compounds too toxic for the intended medicinal purposes.By limiting the claims to the expression "or a physiologically acceptable salt thereof" would overcome the rejection.**

Claims 18-22 are rejected under 35 U.S.C.§ 112 (second par.) on the grounds of failing to define the invention properly.Specifically, the terms "or a tautomer thereof" does not offer a clue as to which hetero-ring or functional moiety exists as a tautomer.Also, in claim 18,"or a group which is cleaved in vivo" is indefinite fails to indicate the precursor moiety to be cleaved and fails to identify the enzyme in the mammalian host that is capable of doing the cleaving. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Claims 19-28 are rejected under 35 U.S.C§ 112(second par on the grounds of failing to define the invention properly.Specifically,claims 19-22 are dependent upon claim 1, which no longer exists in this application.Claim 18 appears to have replaced claim 1 and the dependency should be changed thereto.With respect to claims 23-25, the expression "or a prodrug or double prodrug thereof" is indefinite on its face and clearly an invitation to experimentation.In order to be definite, the claim should identify the specific functional moiety that is going to be cleaved by an enzyme and identify the specific enzyme that will susceptible to carry out the cleaving in order to convert said claimed compound into allegedly **"the drug".**Claims 26-28 are incomplete entities and cannot exist if made independent.They must rely on a proper independent claim.

Claims 29-33 are rejected under 35U.S.C.§112(first par.)on the grounds of an insufficient disclosure of utililty.Specifically, the terms "prevent or" as it pertains to venous or arterial

thrombotic disease" in claim 29 reads on preventing the aging process and is not believable on its face in view of the contemporary knowledge of the art.Claims 30-31 are more specific than claim 29, but still preventing the diseases associated with thrombosis follows the reasoning aforementioned.

Claim 32 alleges preventing metastasis of growth or clot dependent tumors lacks enablement

in the specification in the absence of sufficient data to warrant such an assertion.

In claim 33, the expression "preventing fibrin-dependent inflammatory process represents another assertion that lacks sufficient data in the specification to warrant such a broad statement which reads on preventing each an every form of arthritis, osteoporosis and the like.Mankind would benefit, but being believable in view of the contemporary knoweledge in the art without sufficient data in the specification, is yet another stairways Ex parte Foreman, 230 U.S.P.Q.546 (Bd.of App.& Int.1986); Ex parte Krepelka, 231 U.S.P.Q.746 (Bd.of App. & Int.1986);Ex parte Stevens, 16 U.S.P.Q.2d, 1379 (Bd.of App. & Int.1990: Ex parte Aggawal, 23 U.S.P.Q. 2d, 1334 (Bd.of App. & Int. 1992); In re Brana 34 U.S.P.Q. 2d, 1436 (Fed.Cir.1995). Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alan L.Rotman whose telephone number is (703) 308-5698.

alr

July 10, 1999

Alan L. Rotman

ALAN L. ROTMAN
PRIMARY EXAMINER